

9/14.

Notice of Allowability	Application No.	Applicant(s)	
	09/758,759	HOSTED ET AL.	
	Examiner	Art Unit	
	Tracy Vivemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.
2. ☒ The allowed claim(s) is/are 4,12-17,24,28,29,31 and 32.
3. ☒ The drawings filed on 30 April 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>01/03/2002</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |


KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group 1, claims 1-17, 23-35 and SEQ ID NO 1 in the reply filed on June 11, 2004 is acknowledged. Claims 1-3, 5-11, 18-23, 25-27, 30 and 33-36 have been cancelled by applicant's amendment filed June 11, 2004. Currently, claims 4, 12-17, 24, 28, 29, 31 and 32 are pending in the application.

The information disclosure statements (IDS) submitted on 7/6/2001 and 1/3/2002 have been considered by the examiner.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the specification on page 5 line 32, in the legend for figure 11, the text "AB" has been deleted.

In the specification on page 5 line 32 in the legend for figure 11, the text --AD--has been inserted before the word Everninomicin.

REASONS FOR ALLOWANCE

1. Claims 4, 12-17, 24, 28, 29, 31 and 32 are allowed.
2. The following is an examiner's statement of reasons for allowance: Claim 4 is drawn to the nucleotide sequence defined by SEQ ID NO 1. All other pending claims encompass expression vectors, host cells and methods of obtaining vectors and host cells comprising SEQ ID NO 1. SEQ ID NO 1 is a nucleic acid encoding the everninomicin biosynthetic pathway. Applicants have demonstrated that SEQ ID NO 1 comprises open reading frames that encode proteins including evrJ, an orsellinic acid synthase, evrF, a non-heme oxygenase and evrW, a dTDP-glucose dehydratase and that suicide vector disruption of SEQ ID NO 1 knocks out the everninomicin pathway. SEQ ID NO 1 could be placed into a bacterial artificial chromosome and used to express these known genes.
3. The closest art to the instant invention is as follows: Waitz et al. (US 4735903, April 5, 1988) disclose a variety of *Micromonospora carbonacea* which has an ATCC accession number of 39149. This strain was used to obtain the sequences that encompass the instant invention. Waitz et al. does not anticipate the claimed invention because they do not isolate SEQ ID NO 1.
4. Staffa et al. (US PG PUB 2003/0143666 A1, July 31, 2003) disclose genetic sequences which encode for proteins that direct biosynthesis of everninomicin in *Micromonospora carbonacea*. The disclosed sequences of Staffa et al. do not qualify as prior art; the filing date of the published application

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post-dates the filing date of the instant application and further, Staffa et al. do not disclose the full length of SEQ ID NO 1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The

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USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


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Art Unit 1635

TV
July 7, 2004